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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,786	10/27/2003	Hideo Kato	P24518	1036

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/692,786	KATO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This application is a continuation of SN 09/869,338. Claims 1-11 are pending.
2. Claim 9 provides for the use of a compound of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Cancellation of claim 9 is recommended.

3. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims employed the term “medicament” or “agent” which rendered the claims confusing. It is unclear “what” category of invention are the claims being drawn to i.e. these are hybrid claims intended for composition as well as being used in medicine. If these are composition claims, then the effective quantity and carrier have not been explicitly incorporated. If these claims are method of treating claims, then they are essential duplicates of claims 10-11. Essential duplicate claims are subject to double patenting rejection when one set becomes allowable. It is recommended that one set be canceled.

Art Unit: 1625

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because they are identical to the issued claims 1-24 (see parent US 6,638,951) other than difference in format.

5. Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what does the scope of “preventive” treatment of claim 10 is intended for (2<sup>nd</sup> paragraph rejection). Please note that once a *subject* is being treated for digestive disease i.e. diagnosed with the disease, the treatment can no longer be “preventive”. Therefore, in absence of specific description and enablement for “prevention” in none diseased subject, the specification lacks enablement of such de novo prevention (1<sup>st</sup> paragraph rejection). To the extent that the prevention is in preventing recurrence of symptom or pathology in a diseased subject, this is encompassed in the term “treatment” i.e. a maintenance dose in preventing symptom or pathology from recurrence. Therefore, it is recommended that the term “prevention” be deleted from the claim.

The scope of “improving function of gastrointestinal tract motility” is ambiguous and unclear (2<sup>nd</sup> paragraph rejection). Please note that “improvement” includes both increase motility and decrease motility. A single compound can not both increase and decrease

Art Unit: 1625

gastrointestinal tract motility (1<sup>st</sup> paragraph). If some compounds can increase, other compounds can decrease, then the specification lacks how to pick and choose among the various Markush compounds for the opposite effect on the gastrointestinal tract (1<sup>st</sup> paragraph rejection).

In addition, if the function of the compound is to improve motility, then it lacks enabling description and teaching on how all digestive disease such as ulcer, stomach cancer etc. can be treated by the compounds (1<sup>st</sup> paragraph rejection).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. US 5,500,422.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Ito et al. '422 generically disclosed the claimed compounds for stimulating motility of digestive tract and a specific compound was disclosed as example 46, col. 26; or claim 2 col. 31, and been shown to have GI tract stimulating effect (see col. 11 table 1, example 46).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art is that instead of an ethyl ester, the instant claims having R being a C<sub>3</sub>-C<sub>6</sub> moiety. Generically, Ito et al. '442, (see col. 2

Art Unit: 1625

formula I R4 is lower alkyl i.e. C<sub>1-6</sub> considered by ordinary chemist) taught that lower alkyl esters are optional choices for such modification.

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

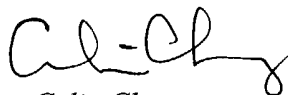
One having ordinary skill in the art would find the instant claims prima facie **because** the replacement of an ethyl group with other lower alkyl not only is expected to have similar activity due to close structural relationship by the court (In re Shetty 195 USPQ 753, Ex parte Ruddy 121 USPQ 427), but also specifically recognized in the field as taught generically by the Ito et al. '422 reference to be expected having similar activity. In absence of unexpected results, mere picking and choosing among the many chain length of the prior art is prima facie obvious. In re Lemin 141 USPQ 814).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Sept. 2, 2004

  
Celia Chang  
Primary Examiner  
Art Unit 1625